

Werley, Michael S

From: Haussmann, Hans-Juergen
Sent: Wednesday, March 19, 2003 3:39 AM
To: Patskan, George J.; Werley, Michael S
Subject: Review of JLI SDS



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HJM Comments SDS
JLI 18Mar03.d...



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Dear George and Mike:

Please find attached my remarks to the document. I was able to write them down, since I omitted all the general remarks made and discussed during the video conference. I also omitted all remarks about grammar or spelling or nomenclature.

Let me point once more to the fact that if we keep the current emphasis on the non-clinical data generated under 'topography' conditions we might be losing ground for all previous tests, e.g., on ingredients, and might need to change our future processes as well. My preference would still be to start with the acceptability testing (as introduced in this sequence in the Introduction), to exploit that for reduced exposure assessment, and finally to bridge and corroborate with the findings of the 'topography' tests.

I don't envy you for your task, and I wish you all the best. Isn't it a great objective to do something the first time, but nevertheless it must be perfect?

Best regards,

Hans-Juergen

Please note that our company name has changed from "INBIFO Institut für biologische Forschung GmbH" to "PHILIP MORRIS Research Laboratories GmbH". This is to express our more than 30-years affiliation with PHILIP MORRIS.

Please also make sure that you are using my new e-mail address: HansJ.Haussmann@pmintl.com.